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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,869	10/31/2006	Ask Puschl	433-US-PCT	2039

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LUNDBECK RESEARCH USA, INC.  
ATTENTION: STEPHEN G. KALINCHAK, LEGAL  
215 COLLEGE ROAD  
PARAMUS, NJ 07652

EXAMINER
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SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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02/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/551,869

Applicant(s)

PUSCHL ET AL.

Examiner

Taofiq A. Solola

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-14, 16, 18-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-14, 16 and 18-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____                                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1</u> .   | 6) <input type="checkbox"/> Other: ____                           |

Claims 1-14, 16, 18-40 are pending in this application.

Claims 15, 17, are cancelled.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14, 16, 18-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Puschl et al., WO 03/029232.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Puschl et al., the instant compounds, composition and method of use for treating affective disorder.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to

a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 16, 18-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al., J. Med. Chem. (1979), Vol. 22(11), pp. 1347-1354, in view of Silverman, The Org. Chem. of Drug Design and Drug Action, (1992) San Diego, Academic Press, Pp. 19.

Applicant claims compounds of formula I, their composition and method of use for treating affective disorder.

Determination of the scope and content of the prior art (MPEP 2141.01)

Martin et al., teach similar compounds their composition and method of use for treating affective disorder. See the abstract, and the examples in Table III, page 1350.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Martin et al., is that in compounds of the prior art, applicant replaced  $-CH_2-$  with  $-S-$ . Some of the compounds of Martin et al., are 3<sup>o</sup> amines instead of 2<sup>o</sup> amines in the instant and some are position isomers of the instant compounds.

Finding of prima facie obviousness--rational and motivation (MPEP 2142.2413)

However, Silverman teaches that replacement of  $-CH_2-$  with  $-S-$  in a compound is expected to produce compounds having similar biological activity (bioisosterism). See page 19, bivalent atoms and groups. See also, *Ex parte Engelhardt*, 208 USPQ 343 (Bd. Pat. App. & Int., 1980); *In re Merck*, 231 USPQ 375 (Fed. Cir. 1986).

Also, 2<sup>o</sup> and 3<sup>o</sup> amines are obvious variants. *Ex parte Bluestone*, 135 USPQ 199 (1961). A novel and useful compound, which is an isomer of a compound of prior art, is prima facie obvious. *In re Norris*, 84 USPQ 458 (1950).

Therefore, the instant invention is prima facie obvious from the teachings of Martin et al., and Silverman. One of ordinary skill in the art would have known to replace  $-CH_2-$  with  $-S-$  in

the compounds of Martin et al., at the time the instant invention was made. The motivation is from knowing that  $-CH_2-$  and  $-S-$  are bioisosteres equivalents.

Alternatively, given the teachings of the prior arts, it would have been obvious to try replacement of  $-CH_2-$  with  $-S-$  in the compounds of Martin et al., at the time the invention was made.

When there is motivation

to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

*KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct 1727,-----, 82 USPQ2d 1385, 1397 (2007).

Alternatively, applicant has done nothing more than substitutes known bioisosteres equivalents in of prior arts' compounds. However, such substitution is obvious from the prior arts and knowledge of bioisosteres equivalents. "When a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *United States v. Adams*, 383 U.S. 49, 50-51 (1966). Cited in *KSR Int. Co. v. Teleflex Inc*, 550 U.S. ----, 82 USPQ2d 1385 (2007). The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR, supra*.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14, 16, 18-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 7,138,407; claims 1-18 of US 7,148,238; and claims 1-29 of US 7,144,884. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is claimed in each US patent listed above the difference being the scope of the compounds.

Claims 1-14, 16, 18-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12, 14, 16-34 of copending Application No. 11/551,188. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is claimed in US '188, the difference being the scope of the compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



**TAOFIQ SOLOLA  
PRIMARY EXAMINER**

Group 1625

January 29, 2008